



PATENT  
Customer No. 22,852  
Attorney Docket No. 08157.0010

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Paul GILSON et al.

Application No.: 09/838,545

Filed: April 20, 2001

For: AN EMBOLIC PROTECTION  
SYSTEM

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)  
) Group Art Unit: 3737  
)  
) Examiner: Unknown  
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)  
)  
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Assistant Commissioner for Patents  
Washington, DC 20231

Sir:

**PRELIMINARY AMENDMENT**

Prior to examination, please amend this application as follows:

**IN THE SPECIFICATION:**

At page 1, between lines 3 and 5, insert the following new paragraph:

--This is a continuation-in-part of Application No. 09/188,472, filed November 9, 1998.--

**REMARKS**

The above amendment to the specification further clarifies that the instant application is a continuation-in-part application of pending Application No. 09/188,472.

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Application No. 09/838,545

If there is any fee due in connection with the filing of this Preliminary Amendment, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: August 20, 2001

By:   
Roland G. McAndrews  
Reg. No. 41,450

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Assistant Commissioner for Patents  
Washington, DC 20231

Sir:

**SUPPLEMENTAL PRELIMINARY AMENDMENT**

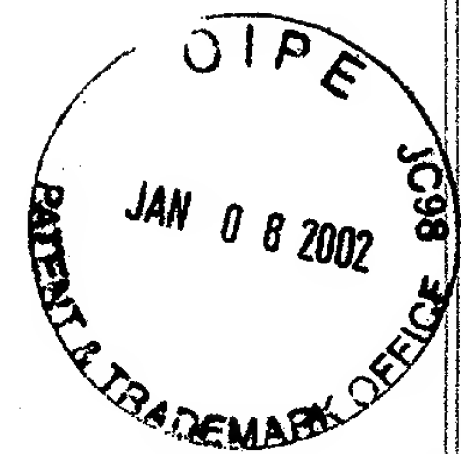
Prior to examination, please further amend the above-identified application as follows:

**IN THE CLAIMS:**

Please cancel claims 35, 48, 60 and 67 without prejudice or disclaimer, and replace claims 3, 5, 6, 9, 10, 13, 14, 18-22, 24, 26-28, 30, 33, 34, 38-43, 45, 51-56, 58, 63, 64 and 66 with the following:

3. (Amended) An embolic protection system as claimed in claim 1 wherein the tubular guidewire path is defined by a tubular sleeve.

5. (Amended) An embolic protection system as claimed in claim 1 wherein the guidewire path is a tubular guidewire path.



6. (Amended) An embolic protection system as claimed in claim 1 wherein the engagement elements comprise a guidewire engagement element on the guidewire and a filter engagement element on the filter, the engagement elements co-operating to provide selective engagement and positioning of the filter with respect to the guidewire.

9. (Amended) An embolic protection system as claimed in claim 7 wherein the guidewire abutment is located proximal of the distal end of the guidewire.

10. (Amended) An embolic protection system as claimed in claim 6 wherein the engagement element of the filter comprises a filter abutment on the filter.

13. (Amended) An embolic protection system as claimed in claim 10 wherein the tubular guidewire path is defined by a sleeve and the filter abutment is provided by the sleeve.

14. (Amended) An embolic protection system as claimed in claim 1 wherein the engagement elements comprise releasable locking elements.

18. (Amended) An embolic protection system as claimed in claim 16 including a tube advancable over the guidewire, the locking ring being located between a distal end of the tube and the filter for retrieval of the filter.

19. (Amended) An embolic protection system as claimed in claim 15 wherein the releasable locking means includes a tether engagable with the filter for retrieving the filter into the retrieval catheter.

20. (Amended) An embolic protection system as claimed in claim 1 comprising deployment means for moving the collapsed filter relative to the distal end of the delivery catheter.

21. (Amended) An embolic protection system as claimed in claim 20 wherein the deployment means comprises a tube which is advancable over the guidewire for engagement with the proximal end of the filter, the tube being movable longitudinally relative to the delivery catheter for deployment of the filter from the distal end of the delivery catheter.

22. (Amended) An embolic protection system as claimed in claim 1 including loading means for loading the filter into the delivery catheter.

24. (Amended) An embolic protection system as claimed in claim 1 including engagement means for engaging the filter within the retrieval catheter.

26. (Amended) An embolic protection system as claimed in claim 24 wherein the engagement means comprises projections on the inner surface of retrieval catheter adjacent the distal end thereof.

27. (Amended) An embolic protection system as claimed in claim 1 wherein the delivery catheter includes an elongate slot disposed in a first sidewall thereof at a first distal location which is spaced a relatively longer distance from the proximal end of the delivery catheter than from the distal end of the delivery catheter, and wherein the inner deployment catheter includes an aperture disposed in a second sidewall thereof at a second distal location which substantially corresponds with said first distal location for said elongate slot, thereby permitting co-operative movement of said filter with respect to said guidewire and associated delivery and deployment catheters for selective deployment of the filter while facilitating the rapid exchange of said catheter and filter assembly over a guidewire without the utilisation of exchange wires or extension wires.

28. (Amended) An embolic protection system as claimed in claim 1 wherein the embolic protection filter comprises a collapsible filter body, the proximal inlet end of the filter body having one or more inlet openings sized to allow blood and embolic material enter the filter body, the distal outlet end of the filter body having a plurality of outlet openings sized to allow through passage of blood but to retain undesired embolic material within the filter body.

30. (Amended) An embolic protection system as claimed in claim 28 comprising a guide olive provided at the distal end of the filter body.

33. (Amended) A system as claimed in claim 30 wherein the guide olive is integral with the filter body.

34. (Amended) A system as claimed in claim 30 wherein the guide olive tapers distally inwardly.

38. (Amended) A method as claimed in claim 36 including the step of moving the guidewire after withdrawal of the retrieval catheter and the collapsed filter from the vasculature to re-position the guidewire in the vasculature.

39. (Amended) A method as claimed in claim 37 wherein the catheter is a catheter for delivery of a diagnostic medium.

40. (Amended) A method as claimed in claim 37 wherein the catheter is a catheter for delivery of a lytic agent.

41. (Amended) A method as claimed in claim 36 wherein the filter is slidably disposed on the guidewire when the filter is in the expanded deployed configuration.

42. (Amended) A method as claimed in claim 36 wherein the filter is rotatably disposed on the guidewire when the filter is in the expanded deployed configuration.

43. (Amended) A method as claimed in claim 36 including the steps of:-  
loading the filter in a collapsed configuration within a delivery catheter;

advancing the delivery catheter and filter over the guidewire to deliver the filter to a desired location; and

deploying the filter from the delivery catheter at the desired location.

45. (Amended) A method as claimed in claim 36 wherein the treatment location is a region of stenosis.

51. (Amended) A catheter as claimed in claim 49 where in the outer catheter tube at least partially comprises a relatively stiff core encased in a more pliable body.

52. (Amended) A catheter as claimed in claim 50 wherein the core is oriented to prevent at least one of elongation of the outer catheter tube and compression of the inner catheter tube.

53. (Amended) A catheter as claimed in claim 49 wherein the core comprises a mesh.

54. (Amended) A catheter as claimed in claim 50 wherein the core comprises a plurality of longitudinally oriented strips of a stiff material.

55. (Amended) A catheter as claimed in claim 50 wherein the core comprises a plurality of circumferentially oriented strips of a stiff material.



56. (Amended) A catheter as claimed in claim 50 wherein the core is of a metallic material.

58. (Amended) A catheter as claimed in claim 50 wherein the pliable body is of a plastics material.

63. (Amended) A device as claimed in claim 61 wherein the frame proximal section comprises one or more frame elements, at least one frame element providing the part of the proximal section spaced distally.

64. (Amended) A device as claimed in claim 62 wherein at least one frame element provides the part of the proximal section extending radially inwardly in alignment with a linking web between adjacent inlet openings.

66. (Amended) A device as claimed in claim 61 wherein the support frame is gold-plated and electropolished.

#### **REMARKS**

In this Amendment, Applicants have canceled claims 35, 48, 60 and 67 without prejudice or disclaimer, and amended claims 3, 5, 6, 9, 10, 13, 14, 18-22, 24, 26-28, 30, 33, 34, 38-43, 45, 51-56, 58, 63, 64 and 66. The changes to the pending claims are indicated with strikethrough and underlining in the Appendix of this Amendment, as required by new rule 37 C.F.R. § 1.121(c)(1)(ii). Accordingly, claims 1-34, 36-47, 49-59 and 61-66 are pending in this application.


This Preliminary Amendment in no way manifests an intent on the part of Applicants to narrow the scope of the originally-filed claims. The Examiner is respectfully requested to consider the above Preliminary Amendment prior to examination of the application.

If there are any other fees due in connection with the filing of this amendment, please charge the fees to Deposit Account No. 06-0916. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our deposit account.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: January 8, 2002

By:   
Roland G. McAndrews  
Reg. No. 41,450

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## APPENDIX TO AMENDMENT

Applicants submit the following requested changes to the present application with strikethrough and underlining for the Examiner's convenience as required by new rule 37 C.F.R. § 1.121(c)(1)(ii). This APPENDIX is not intended to be entered into the application.

### IN THE CLAIMS:

The changes requested of claims 3, 5, 6, 9, 10, 13, 14, 18-22, 24, 26-28, 30, 33, 34, 38-43, 45, 51-56, 58, 63, 64 and 66 are as follows:

3. (Amended) An embolic protection system as claimed in claim 1 ~~or 2~~ wherein the tubular guidewire path is defined by a tubular sleeve.

5. (Amended) An embolic protection system as claimed in ~~any preceding~~ claim 1 wherein the guidewire path is a tubular guidewire path.

6. (Amended) An embolic protection system as claimed in ~~any preceding~~ claim 1 wherein the engagement elements comprise a guidewire engagement element on the guidewire and a filter engagement element on the filter, the engagement elements co-operating to provide selective engagement and positioning of the filter with respect to the guidewire.

9. (Amended) An embolic protection system as claimed in claim 7 ~~or 8~~ wherein the guidewire abutment is located proximal of the distal ~~and~~ end of the guidewire.

10. (Amended) An embolic protection system as claimed in ~~any of claims 6 to 9~~ claim 6 wherein the engagement element of the filter comprises a filter abutment on the filter.

13. (Amended) An embolic protection system as claimed in ~~any of claims 10 to 12~~ claim 10 wherein the tubular guidewire path is defined by a sleeve and the filter abutment is provided by the sleeve.

14. (Amended) An embolic protection system as claimed in ~~any preceding~~ claim 1 wherein the engagement elements comprise releasable locking elements.

18. (Amended) An embolic protection system as claimed in ~~claims 16 or 17~~ claim 16 including a tube advancable over the guidewire, the locking ring being located between a distal end of the tube and the filter for retrieval of the filter.

19. (Amended) An embolic protection system as claimed in ~~any of claims 15 to 18~~ claim 15 wherein the releasable locking means includes a tether engagable with the filter for retrieving the filter into the retrieval catheter.

20. (Amended) An embolic protection system as claimed in ~~any preceding~~ claim 1 comprising deployment means for moving the collapsed filter relative to the distal end of the delivery catheter.

21. (Amended) An embolic protection system as claimed in ~~claim 24~~ 20 wherein the deployment means comprises a tube which is advancable over the guidewire for engagement with the proximal end of the filter, the tube being movable longitudinally relative to the delivery catheter for deployment of the filter from the distal end of the delivery catheter.

22. (Amended) An embolic protection system as claimed in ~~any preceding~~ claim 1 including loading means for loading the filter into the delivery catheter.

24. (Amended) An embolic protection system as claimed in ~~any preceding~~ claim 1 including engagement means for engaging the filter within the retrieval catheter.

26. An embolic protection system as claimed in ~~claim 24 or 25~~ wherein the engagement means comprises projections on the inner surface of retrieval catheter adjacent the distal end thereof.

27. (Amended) An embolic protection system as claimed in ~~any preceding~~ claim 1 wherein the delivery catheter includes an elongate slot disposed in a first sidewall thereof at a first distal location which is spaced a relatively longer distance from the proximal end of the delivery catheter than from the distal end of the delivery catheter, and wherein the inner deployment catheter includes an aperture disposed in a second sidewall thereof at a second distal location which substantially corresponds with said first distal location for said elongate slot, thereby permitting co-operative movement of said filter with respect to said guidewire and associated delivery and deployment catheters for selective deployment of the filter while facilitating the rapid exchange of said catheter and filter assembly over a guidewire without the utilisation of exchange wires or extension wires.

28. (Amended) An embolic protection system as claimed in ~~any preceding~~ claim 1 wherein the embolic protection filter comprises a collapsible filter body, the proximal inlet end of the filter body having one or more inlet openings sized to allow blood and embolic material enter the filter body, the distal outlet end of the filter body having a plurality of outlet openings sized to allow through passage of blood but to retain undesired embolic material within the filter body.

30. (Amended) An embolic protection system as claimed in ~~claim 28 or 29~~ claim 28 comprising a guide olive provided at the distal end of the filter body.

33. (Amended) A system as claimed in ~~any of claims 30 to 32~~ claim 30 wherein the guide olive is integral with the filter body.

34. (Amended) A system as claimed in ~~any of claims 30 to 33~~ claim 30 wherein the guide olive tapers distally inwardly.

38. (Amended) A method as claimed in claim 36 ~~or 37~~ including the step of moving the guidewire after withdrawal of the retrieval catheter and the collapsed filter from the asculature to re-position the guidewire in the vasculature.

39. (Amended) A method as claimed in claim 37 ~~or 38~~ wherein the catheter is a catheter for delivery of a diagnostic medium.

40. (Amended) A method as claimed in claim 37 ~~or 38~~ wherein the catheter is a catheter for delivery of a lytic agent.

41. (Amended) A method as claimed in ~~any of claim 36 to 40~~ claim 36 wherein the filter is slidably disposed on the guidewire when the filter is in the expanded deployed configuration.

42. (Amended) A method as claimed in ~~any of claims 36 to 41~~ claim 36 wherein the filter is rotatably disposed on the guidewire en the filter is in the expanded deployed configuration.

43. (Amended) A method as claimed in ~~any of claims 36 to 42~~ claim 36 including the steps of:-  
loading the filter in a collapsed configuration within a delivery catheter;  
advancing the delivery catheter and filter over the guidewire to deliver the filter to a desired location; and  
deploying the filter from the delivery catheter at the desired location.

45. (Amended) A method as claimed in ~~any of claims 36 to 44~~ claim 36 wherein the treatment location is a region of stenosis.

51. (Amended) A catheter as claimed in claim 49 ~~or 50~~ where in the outer catheter tube at least partially comprises a relatively stiff core encased in a more pliable body.

52. (Amended) A catheter as claimed in claim 50 ~~or 51~~ wherein the core is oriented to prevent at least one of elongation of the outer catheter tube and/or compression of the inner catheter tube.

53. (Amended) A catheter as claimed in ~~any of claims 49 to 52~~ claim 49 wherein the core comprises a mesh.

54. (Amended) A catheter as claimed in ~~any of claims 50 to 53~~ claim 50 wherein the core comprises a plurality of longitudinally oriented strips of a stiff material.

55. (Amended) A catheter as claimed in ~~any of claims 50 to 54~~ claim 50 wherein the core comprises a plurality of circumferentially oriented strips of a stiff material.

56. (Amended) A catheter as claimed in ~~any of claims 50 to 55~~ claim 50 wherein the core is of a metallic material.

58. (Amended) A catheter as claimed in ~~any of claims 50 to 57~~ claim 50 wherein the pliable body is of a plastics material.

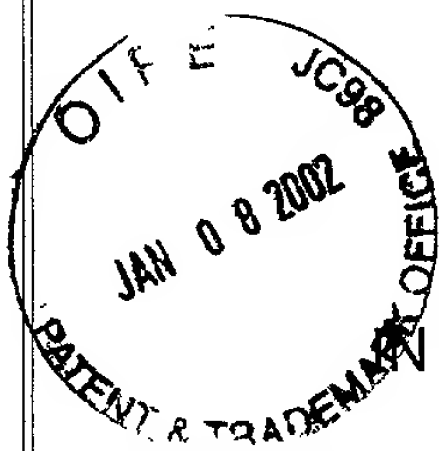
63. (Amended) A device as claimed in ~~claims 61 or 62~~ claim 61 wherein the frame proximal section comprises one or more frame elements, at least one frame element providing the part of the proximal section spaced distally.

64. (Amended) A device as claimed in claim 62 or 63 wherein at least one frame element provides the part of the proximal section extending radially inwardly in alignment with a linking web between adjacent inlet openings.

66. (Amended) A device as claimed in ~~any of claims 61 to 65~~ claim 61 wherein the support frame is gold-plated and electropolished.

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Assistant Commissioner for Patents  
Washington, DC 20231

Sir:

**SUBMISSION OF FORMAL DRAWINGS**


Subject to the approval of the Examiner, please replace the originally filed drawings with the 35 sheets of formal drawings filed herewith (Figs. 1-85). If the formal drawings for any reason are not in full compliance with the pertinent statutes and regulations, please so advise the undersigned.

If any fees are necessary for the submission of these formal drawings, please charge our deposit account no. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: January 8, 2002

By:   
Roland G. McAndrews, Jr.  
Reg. No. 41,450

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